

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) Pharmaceutical composition, containing oxcarbazepine having a particle size distribution determined by laser beam diffraction (Malvern Mastersizer, dry dispersion), as follows:

d(0.1) - 20 μ m - 70 μ m
d(0.5) = 70 μ m - 175 μ m
d(0.9) - 200 μ m - 450 μ m

, which releases the following quantities of oxcarbazepine:

15 min: 55 to 85%
30 min: 75 to 95%
45 min: 85 to 100%
60 min: 90 to 100%

in vitro according to the USP paddle method (USP 24, method 724, app. 2 in 1 L 2 wt.-% sodium dodecylsulphate solution as release medium, at a stirring speed of 75 rpm).

2. (Original) Pharmaceutical composition according to claim 1, containing oxcarbazepine, which releases the following quantities of oxcarbazepine:

15 min: 65 to 80%
30 mm: 85 to 95%
45 min: 90 to 100%
60 min: 95 to 100%

in vitro according to the USP paddle method (USP 24, method 724, app. 2 in 1 L 2 wt.-% sodium dodecylsulphate solution as release medium, at a stirring speed of 75 rpm).

3. (Currently amended) Pharmaceutical composition according to claim 1, which produces the following plasma concentrations of oxcarbazepine:

1.5 to 2 hours	0.2 to 0.6 mg/L
5.5 to 6.5 hours	0.1 to 0.3 mg/L
11 to 13 hours	0.1 to 0.2 mg/L
23 to 25 hours	0.0 to 0.2 mg/L

in vivo after peroral intake of the pharmaceutical composition, in such a way that 600 mg oxcarbazepine are administered, and which produces the following plasma concentrations of monohydroxydihydrocarbamazepine:

1.5 to 2 hours	1 to 4 mg/L
5.5 to 6.5 hours	3 to <u>[S] 5</u> mg/L
11 to 13 hours	3 to 5 mg/L
23 to 25 hours	2.5 to 4.5 mg/L.

4. (Original) Pharmaceutical composition according to claim 1, which, *in vivo* after peroral intake of the pharmaceutical composition, in such a way that 600 mg oxcarbazepine are administered, produces an average plasma level of monohydroxydihydrocarbamazepine of 3 to 5 mg/mL in the period from 4 hours after intake to 21 hours after intake.

5. (Currently amended) Pharmaceutical composition according to claim 1, which, *in vivo* after peroral intake of the pharmaceutical composition, in such a way that 600 mg oxcarbazepine are administered, produces a maximum plasma level (C_{max}) of monohydroxydihydrocarbamazepine of 3 to [[S]] 5 mg/mL.

6. (Currently amended) Process for the preparation of a pharmaceutical composition according to claim 1, ~~in which comprising forming a mixture which, relative to its total weight, contains comprising:~~

- a. 60 to 95 wt.-% oxcarbazepine,
- b. 3 to 30 wt.-% microcrystalline cellulose,
- c. 1 to 20 wt.-% ammonium methacrylate copolymer and/or polymethacrylic acid polymer,
- d. 0.05 to 4 wt.-% disintegrant and
- e. dye

~~is prepared and then compacted~~ compacting the mixture.

7. (Currently amended) Process according to claim 6, ~~in which a~~ wherein the mixture which, relative to its total weight, contains comprises:

- a. 80 to 90 wt.-% oxcarbazepine,
- b. 5 to 15 wt.-% microcrystalline cellulose,
- c. 2 to 10 wt.-% ammonium methacrylate copolymer and/or polymethacrylic acid polymer,
- d. 0.1 to 2 wt.-% disintegrant and
- e. dye

~~is prepared and then compacted~~.

8. (Original) Process according to claim 6, in which the compacted material is screened and packed into capsules or into pouches unchanged or optionally provided with excipients.

9. (Original) Process according to claim 6, in which after the compacting, relative to 100 parts by weight of the compacted material,

- f. 0.2 to 5 parts by weight magnesium stearate and
- g. 10 to 50 parts by weight microcrystalline cellulose

are added and the thus-obtained mixture is further processed into a tablet.

10. (Currently amended) Process for the preparation of a pharmaceutical composition according to claim 1, ~~in which comprising preparing~~ preparing a granulated material which, relative to its total weight, contains

- A. 60 to 95 wt.-% oxcarbazepine
- B. 3 to 30 wt.-% microcrystalline cellulose
- C. 0.05 to 4 wt.-% disintegrant
- D. 1 to 20 wt.-% polymer
- E. 0.2 to 5 wt.-% plasticizer
- F. 0 to 5 wt.-% anti-adherent agent
- G. dye

said granulated mixture [[is]] prepared in a fluidized bed or in a high-shear mixer with the addition of water.

11. (Currently amended) Process according to claim 10, in which the granulated material, relative to its total weight, contains:

- A. 80 to 90 wt.-% oxcarbazepine
- B. 5 to 15 wt.-% microcrystalline cellulose
- C. 0.1 to 2 wt.-% disintegrant
- D. 2 to 10 wt.-% polymer
- E. 0.4 to 2.5 wt.-% plasticizer
- F. 0 to 2.5 wt.-% anti-adherent agent
- G. dye[[q.s]].

12. (Original) Process according to claim 10, in which, relative to 100 parts by weight of the granulated material,

- H. 0.2 to 0.5 parts by weight tablet lubricant and
- I. 10 to 50 parts by weight microcrystalline cellulose

are added and the thus-obtained mixture is further processed into a tablet.

13. (Currently amended) Process according to claim 6, in which the compacted material, using relative to 100 parts by weight of the compacted material,

- F. 0.5 to 10 parts by weight polymethacrylic acid copolymer
- G. 0.025 to 2 parts by weight plasticizer
- H. 0.025 to 2 parts by weight anti-adherent agent

is coated with a film in a[[the]] high-shear mixer with the addition of water.

14. (Original) Process according to claim 13, in which, relative to 100 parts by weight of the film-coated compacted material,

- I. 0.2 to 0.5 parts by weight tablet lubricant and
- J. 10 to 50 parts by weight microcrystalline cellulose

are added and the thus-obtained mixture is further processed into a tablet.

15. (Currently amended) Process according to claim 9, in which the tablets are coated with a film in a drum coater, using water and, wherein the film comprises relative to 100 parts by weight of the tablet,

- H. 0.5 to 10 parts by weight polymethacrylic acid copolymer
- I. 0.025 to 2 parts by weight plasticizer
- J. 0.025 to 2 parts by weight anti-adherent agent, and
- K. dye and/or pigments.

16. (Original) Process according to claim 9, in which the tablets are coated with a film in a drum coater, using water and, relative to 100 parts by weight of the tablets,

- H. 0.5 to 10 parts by weight film former
- I. 0.0 to 2 parts by weight plasticizer
- J. 0.005 to 2 parts by weight anti-adherent agent, and
- K. dye and/or pigments.

17. (Currently amended) Pharmaceutical composition which is obtained according to the process of [[to]]claim 7.

18. (Original) A process for the treatment of primarily generalized tonic-clonic seizures and/or focal seizures, with or without secondary generalization, comprising perorally administering an effective amount of the pharmaceutical composition according to claim 1.

19. (Original) A process for the treatment of neuralgic and cerebrovascular pains or for alcohol disintoxication, comprising perorally administering an effective amount of the pharmaceutical composition according to claim 1.

20. (Canceled).

21. (Currently amended) Pharmaceutical composition according to claim 1, wherein the particle size distribution of oxcarbazepine determined by laser beam diffraction (Malvern Mastersizer, dry dispersion) is as follows contains oxcarbazepine of the following particle size distribution:

~~Determination by laser beam diffraction (Malvern Mastersizer, dry dispersion)~~

d(0.1) :[[=]] 20[[5]] μm - 45 μm
d(0.5) :[[=]] 90 μm - 125 μm
d(0.9) :[[=]] 250 μm - 350 μm .

22. (Canceled).

23. (New) Process for the preparation of a pharmaceutical composition according to claim 1, comprising forming a mixture comprising:

- a. 60 to 95 wt. % oxcarbazepine,
- b. 3 to 30 wt. % microcrystalline cellulose,
- c. 1 to 20 wt. % ammonium methacrylate copolymer and/or polymethacrylic acid polymer,
- d. 0.05 to 4 wt. % disintegrant and
- e. dye

and then compacting the mixture, screening the compacted material and packing the screened material into capsules or into pouches wherein the packed material has a particle size distribution determined by sieve analysis (Retsch AS control) as follows:

> 1.000 mm : 0% - 5%
1.000 mm - 0.500 mm : 35% - 65%
0.500 mm - 0.250 mm : 15% - 35%
0.250 mm - 0.125 mm : 10% - 25%
0.125 mm - 0.063 mm : 0% - 15%
< 0.063 mm : 0% - 5% .

24. (New) The process according to claim 23, wherein the pharmaceutical composition releases the following quantities of oxcarbazepine:

15 min: 65 to 80%
30 min: 85 to 95%
45 min: 90 to 100%
60 min: 95 to 100%

in vitro according to the USP paddle method (USP 24, method 724, app. 2 in 1 L 2 wt.-% sodium dodecylsulphate solution as release medium, at a stirring speed of 75 rpm).

25. (New) The process according to claim 23, wherein the pharmaceutical composition produces the following plasma concentrations of oxcarbazepine:

1.5 to 2 hours	0.2 to 0.6 mg/L
5.5 to 6.5 hours	0.1 to 0.3 mg/L
11 to 13 hours	0.1 to 0.2 mg/L
23 to 25 hours	0.0 to 0.2 mg/L

in vivo after peroral intake of the pharmaceutical composition, in such a way that 600 mg oxcarbazepine are administered, and which produces the following plasma concentrations of monohydroxydihydrocarbamazepine:

1.5 to 2 hours	1 to 4 mg/L
5.5 to 6.5 hours	3 to 5 mg/L
11 to 13 hours	3 to 5 mg/L
23 to 25 hours	2.5 to 4.5 mg/L.

26. (New) The process according to claim 23, which, *in vivo* after peroral intake of the pharmaceutical composition, in such a way that 600 mg oxcarbazepine are administered, produces an average plasma level of monohydroxydihydrocarbamazepine of 3 to 5 mg/mL in the period from 4 hours after intake to 21 hours after intake.

27. (New) The process according to claim 23, which, *in vivo* after peroral intake of the pharmaceutical composition, in such a way that 600 mg oxcarbazepine are administered, produces a maximum plasma level (C_{max}) of monohydroxydihydrocarbamazepine of 3 to 5 mg/mL.

28. (New) Process according to claim 23, wherein the mixture comprises:

- a. 80 to 90 wt.-% oxcarbazepine,
- b. 5 to 15 wt.-% microcrystalline cellulose,
- c. 2 to 10 wt.-% ammonium methacrylate copolymer and/or polymethacrylic acid polymer,
- d. 0.1 to 2 wt.-% disintegrant and
- e. dye.

29. (New) Process according to claim 23, in which the compacted material includes an excipient.

30. (New) Process according to claim 23, in which after the compacting, relative to 100 parts by weight of the compacted material,

- f. 0.2 to 5 parts by weight magnesium stearate and
- g. 10 to 50 parts by weight microcrystalline cellulose

are added and the thus-obtained mixture is further processed into a tablet.

31. (New) Process for the preparation of a pharmaceutical composition according to claim 23, wherein said granulated mixture is prepared in a fluidized bed or in a high-shear mixer with the addition of water.

32. (New) Process according to claim 28, wherein said granulated mixture is prepared in a fluidized bed or in a high-shear mixer with the addition of water.

33. (New) Process according to claim 32, in which, relative to 100 parts by weight of the granulated material,

- H. 0.2 to 0.5 parts by weight tablet lubricant and
- I. 10 to 50 parts by weight microcrystalline cellulose

are added and the thus-obtained mixture is further processed into a tablet.

34. (New) Process according to claim 23, in which the compacted material, relative to 100 parts by weight of the compacted material is coated with a film in a high-shear mixer with the addition of water comprising:

- F. 0.5 to 10 parts by weight polymethacrylic acid copolymer
- G. 0.025 to 2 parts by weight plasticizer, and
- H. 0.025 to 2 parts by weight anti-adherent agent.

35. (New) Process according to claim 34, in which, relative to 100 parts by weight of the film-coated compacted material,

- I. 0.2 to 0.5 parts by weight tablet lubricant and
- J. 10 to 50 parts by weight microcrystalline cellulose

are added and the thus-obtained mixture is further processed into a tablet.

36. (New) Process according to claim 30, in which the tablets are coated with a film in a drum coater, using water and, wherein the film comprises relative to 100 parts by weight of the tablet,

- h. 0.5 to 10 parts by weight polymethacrylic acid copolymer
- i. 0.025 to 2 parts by weight plasticizer
- j. 0.025 to 2 parts by weight anti-adherent agent, and
- k. dye and/or pigments.

37. (New) Process according to claim 30, in which the tablets are coated with a film in a drum coater, using water and, wherein the film comprises relative to 100 parts by weight of the tablets,

- h. 0.5 to 10 parts by weight film former
- i. 0.0 to 2 parts by weight plasticizer
- j. 0.005 to 2 parts by weight anti-adherent agent, and
- k. dye and/or pigments.

38. (New) Pharmaceutical composition which is obtained according to the process of claim 28.

39. (New) A process for the treatment of primarily generalized tonic-clonic seizures and/or focal seizures, with or without secondary generalization, comprising perorally administering an effective amount of the pharmaceutical composition according to claim 23.

40. (New) A process for the treatment of neuralgic and cerebrovascular pains or for alcohol disintoxication, comprising perorally administering an effective amount of the pharmaceutical composition according to claim 23.